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09/942,137	08/29/2001	Christopher M. Angelucci	001227.0085	6603

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EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/942,137

Applicant(s)

ANGELUCCI ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 13-21, 23-25, 53-58, 60, 62-66 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-21, 23-25, 53-58, 60, 62-66, 69-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 16-21,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucherman et al. (5,836,948).

Zucherman et al disclose an implant for use in a patient's spinal column, the implant comprising: a body portion having a length, a width, a depth, and configured to be insertable between first and second bone segments, the body portion having an outer surface forming a hollow region; as best seen in FIGS. 1,2, the hollow region comprising most of the volume of the body portion, the body portion further having first and second open ends; as set forth in column 3, line 34, wherein at least one of the first and second open ends comprises a single bone receiving channel (26,28) extending there across that has a first depth measured from the through of the channel to the first side of the outer surface at the at least one end, the first side extending along the length of the body portion, the channel also having a second depth measured from the through of the channel to a second side of the outer surface at the at least one

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end, the second side extending along the length of the body portion, the second side opposite the first side, the first and second depths having different measurements, the channel configured to engage at least one of the first and second bone segments; as set forth in column 15, lines 55-67, column 16, lines 1-67, column 17, lines 1-9; and as best seen in FIGS. 63-66, 74-78.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 7, 8, 13, 14, 15, 70, 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (5,836,948) in view of Sander et al. (7,048,762).

It is noted that Zucherman et al did not teach of an implant made of bone allograft material wherein a portion of the first and second ends comprises demineralized cortical bone wherein the bone is obtained from a cross-section of a donor bone having an intramedullary canal, and wherein the inner surface of the implant is defined by the intramedullary canal of the donor bone and the volume of the hollow region is greater than the intramedullary canal of the donor bone. However, in a similar art, Sander et al evidence the use of an elongated cortical bone implant taking form the long bone to increase the size of the canal

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to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

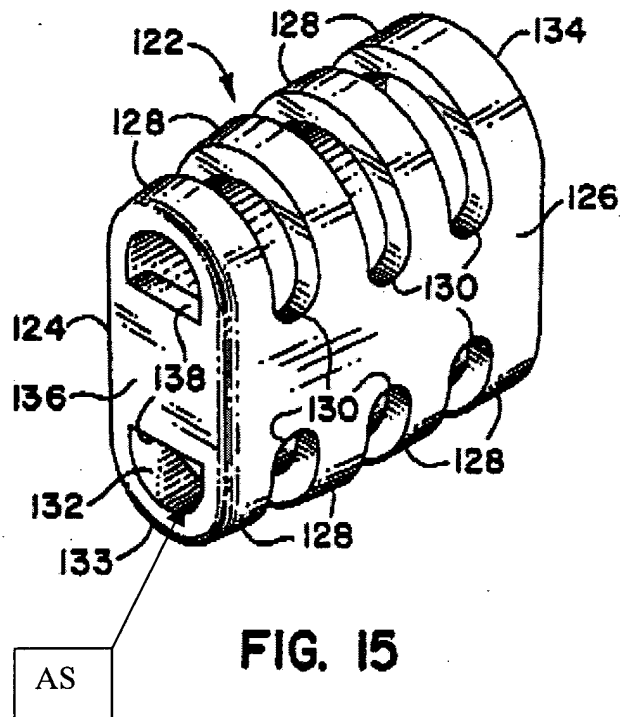
Therefore, given the teaching of Sander et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Zucherman et al, as taught by Sander et al., to increase the size of the canal to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

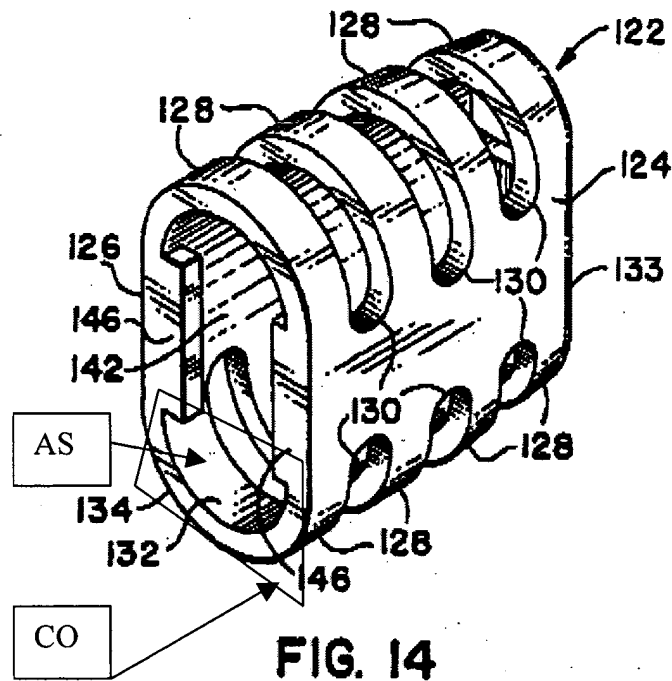
Claims 23-25, 53-58, 60,6-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. (5,458,638) In view of Sander et al. (7,048,762).

Kuslich et al. teach an implant for use in a patient's spinal column, the implant comprising: a tubular body having a length, a width, a depth, a longitudinal axis, and an outer surface and an inner surface forming a thin tubular wall, the perimeter of the outer surface having a substantially oval, circular, or elliptical shape, the body further having first and second ends orthogonal to the longitudinal axis, at least one of the first and second ends comprising a cutout 132 configured to engage and retain a bone segment, the cutout 132 comprising a centerline running parallel to the implant longitudinal axis dividing the ends, the centerline of the at least one cutout 132 being offset from the longitudinal axis; the at least one cutout 132 has a substantially concave arcuate shape AS which is angled relative to flat face FF; the perimeter of the outer surface of the implant being substantially elliptical; further comprising at least one surface 130 defining

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a hole in communication with said outer surface and said inner surface, suitable for attaching a suture to secure said implant to at least one of said first and second bone segments; wherein the implant is fabricated of biocompatible metal (titanium recited in lines 44-45 of column 8); wherein the second end also comprises a cutout CO having a substantially concave arcuate shape AS (see Fig. 14 below).





It is noted that Kuslich et al did not teach of an implant made of bone allograft material wherein a portion of the first and second ends comprises demineralized cortical bone wherein the bone is obtained from a cross-section of a donor bone having an intramedullary canal, and wherein the inner surface of the implant is defined by the intramedullary canal of the donor bone and the volume of the hollow region is greater than the intramedullary canal of the donor bone. However, in a similar art, Sander et al evidence the use of an elongated cortical bone implant taking form the long bone to increase the size of the canal to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

Therefore, given the teaching of Sander et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the device of Zucherman et al, as taught by Sander et al., to increase the size of the canal to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

Claims 4,57, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich/Sander et al. as applied to claims 53 and 72 above, and further in view of the following. Kuslich et al. teach all of the limitations of the present invention except the length ranging from about 11.5 to about 15.5 millimeters, the width ranges from about 8 to about 9 millimeters and the depth ranges from about 5.5 to about 6.5 millimeters and wherein the tubular wall has a thickness of about 1 millimeter.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Kuslich et al. such that the length ranges from about 11.5 to about 15.5 millimeters, the width ranges from about 8 to about 9 millimeters and the depth ranges from about 5.5 to about 6.5 millimeters and wherein the tubular wall has a thickness of about 1 millimeter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich/Sander et al. in view of Paul et al. as applied to claim 59 above, and further in view of the following. The combination taught by Kuslich et al. in view of Paul et al. teaches all of the imitations of the present invention except at last a

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portion of at least one of said first and second ends is comprised of demineralized cortical bone.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use demineralized, cortical, allograft bone to construct the entire device of the combination of Kuslich et al. in view of Paul et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Amendment

Applicant's arguments with respect to claims 1-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
February 4, 2008